

## REMARKS

Claims 18-35 are pending in the application. Claims 18-35 were rejected under the judicially created doctrine of obvious-type double patenting as described on pages 2-3 of the Office Action. Claims 18-35 were rejected under 35 U.S.C. §103(a), as described on pages 4-5 of the Office Action. Claims were rejected under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. § 103, as described on pages 5-6 of the Office Action. Claim 18 is the only independent claim.

In a chromatography measuring device in accordance with the present application, moisture evaporation does not occur in the region where an applied liquid sample is adherently covered with the liquid-impermeable sheet material, and the liquid sample permeates downstream of the chromatography device by a capillary phenomenon. When the liquid sample reaches the open part which is not adherently covered with the liquid-impermeable sheet material, moisture evaporation is progressed and the sample is dried. On the other hand, the liquid sample is held in a sample application part, so that the liquid sample is developed in the chromatographic downstream direction without flowing back.

The present invention therefore provides a device with high sensitivity and high performance, in which the permeation direction and permeation condition of the liquid sample are made uniform, in which the liquid sample and a marker reagent flowing for a definite period of time can flow at uniform concentrations, and in which a water-adsorbing part for adsorbing the sample need not be provided in the downstream region. Accordingly, the number constituent members of the device are reduced and further, the process of manufacturing a specimen is simplified.

Independent claim 18 is drawn to a chromatography measuring device comprising, *inter alia*, a chromatographic test strip and a liquid-impermeable sheet material adherently covering the chromatographic test strip. Further, the chromatographic test strip of claim 18 is required to have a first end region on a chromatographic upstream side operable to receive an application of a sample and a second end region on a chromatographic downstream side with respect to permeation of the sample. Claim 18 further requires the first and second end regions to each have a top surface. Further, claim 18 the liquid-impermeable sheet material to “not cover said top surface of said first end region and said top surface of said second end region.” More particularly, claim 18 requires the

liquid-impermeable sheet material to inherently cover “**a surface other than said top surface of said first end region and said top surface of said second end region.**”

It is respectfully submitted that the prior art of record fails to teach the above-identified limitations. Further, it is respectfully submitted that the present invention would not have been obvious in view of the applied prior art.

As discussed on page 2 of the Office Action, claims 1-29 of the ‘842 reference do not teach or suggest that the liquid-impermeable sheet material does not cover the top surface of the first end region and the top surface of the second end region.

It is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to combine the teachings of any one of Nakaya, Mochizuki nor Takahashi with the teachings of the ‘842 reference as suggested by the Office Action within the meaning of 35 U.S.C. § 103.

If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make proposed modification. *In re Gordon*, 221 USPQ 1125 (*Fed. Cir. 1984*). Column 10, lines 58 through column 11, line 3 of the ‘842 reference indicates that because the upper surface and side surfaces of the chromatographic quantitative assay device are covered by close adhesion with the liquid-impermeable sheet member 7 except for a part for adding the liquid sample, it is possible to prevent vaporization of the water and to make infiltration state of the liquid sample uniform. The cited portion of the text further indicates that in the conventional method, because the marker reagent with high concentration flows out at once due to centralization of the marker reagent at a pointed end of the liquid sample, there remains some of the mark reagent which does not react.

Accordingly, explicit teachings of the ‘842 reference indicates that it is critical that the liquid-impermeable sheet member 7 cover the upper surface and side surface of the chromatographic quantitative assay device except for a part for adding the liquid sample.

It is respectfully submitted that the proposed modifications of the ‘842 device as proposed by the Examiner would render the ‘842 device unsatisfactory for its intended purpose. In particular: “spaces 9 in the coloring region, in addition to the sample addition region, enhanced detection accuracy,” as disclosed in Nakaya; “use of a hole in addition to the sample addition reagent for venting air” as disclosed in Mochizuki; and “tearing off portions of the moisture proof sheet for

sample addition and as a confirmation window,” as taught in Takahashi would enable vaporization of water in the device of the ‘842 reference and therefore render the device unsuitable for its intended purpose.

In light of *in re Gordon*, as discussed above, it is therefore respectfully submitted that it would not have been obvious within the meaning of 35 U.S.C. § 103 to combine the teachings of Nakaya, Mochizuki and Takahashi with the claims of the ‘842 patent to arrive at the present invention.

In light of the above discussion, it is respectfully submitted that it would not have been obvious to combine the teachings of claims 1-29 of the ‘842 reference with any one of Nakaya, Mochizuki and Takahashi within the meaning of the judicially created doctrine of obviousness-type double patenting. Therefore, it is respectfully requested that the rejection of claim 18-35 under the judicially created doctrine of obviousness-type double patenting be withdrawn.

It is respectfully submitted that claims 18-35 are novel over each of Nakaya, Mochizuki and Takahashi within the meaning of 35 U.S.C. § 102(b) for the following reasons.

As discussed above, claim 18 requires that the liquid-impermeable sheet material does not cover the top surface of the first end region and the top surface of the second end region. As illustrated in Fig. B of Nakaya, Figs. (A) and (B) of Takahashi and Fig. 1 of Mochizuki, each of the references fail to teach this limitation.

As anticipation under 35 U.S.C. § 102 requires that each and every element of the claim be disclosed in a prior art reference, *Akzo N. V. v. U.S. Int’l Trade Commission*, 808 F.2d 1471 (Fed. Cir. 1986), based on the foregoing, it is clear that Nakaya, Mochizuki and Takahashi does not anticipate claim 18.

Furthermore, since claims 19-35 are dependent upon claim 18, and therefore include all the limitations thereof, Applicants submit that claims 19-35 additionally novel over each of Nakaya, Mochizuki and Takahashi, within the meaning of 35 U.S.C. § 102(b).

In light of the above discussion, it is respectfully requested that the rejection of claims 18-35 under 35 U.S.C. § 102(b) be withdrawn.

It is respectfully submitted that claims 18-35 are patentable over the prior art of record within the meaning of 35 U.S.C. § 103, for the following reasons.

Applicants note that page 4 of the Office Action asserts that the discussion on pages 1-4 of the Specification is “conceded to be old.” It is respectfully submitted that which is described on pages 1-4 of the Specification is “BACKGROUND ART.” Further, the discussion on pages 1-4 fails to include the phrase “prior art” within the meaning of 35 U.S.C. § 102(b). On the contrary, the discussion on pages 1-4 uses the word “conventional.” Accordingly, it is respectfully submitted that the discussion on pages 1-4 is not admitted prior art within the meaning of 35 U.S.C. § 102. Accordingly, it is respectfully submitted that the discussion on pages 1-4 of the Specification is not applicable prior art.

Nevertheless, as described on page 4 of the Office Action, that which is conceded to be old on pages 1-4 of the Specification fails to teach “use of a liquid-impermeable sheet in two regions that the liquid-impermeable sheet material do not cover.” More specifically, it is respectfully submitted that the subject matter discussed in the background art of the present application fails to teach a liquid-impermeable sheet material that does not cover a top surface of the first end region and a top surface of the second end region.

It is respectfully submitted that Nakaya, Mochizuki and Takahashi fails to teach the shortcomings of that which is conceded to be old on pages 1-4 of the Specification such that a combination (even if the discussion on pages 1-4 of the present application was applicable prior art, which it is not) would teach that which is required in independent claim 18.

Specifically, as discussed above, neither Nakaya, Mochizuki nor Takahashi teach a liquid-impermeable sheet material that does not cover the top surface of the first end region and the top surface of the second end region as required in independent claim 18.

Because neither Nakaya, Mochizuki or Takahashi teaches a liquid-impermeable sheet material that does not cover a top surface of the first end region and a top surface of the second end region, it is respectfully submitted that a combination of the teachings of Nakaya, Mochizuki and Takahashi fails to teach that which is required in independent claim 18.

In light of the above discussion, it is respectfully submitted that claim 18 is patentable over the applied prior art within the meaning of 35 U.S.C. § 103.

Because claims 19-35 are dependent upon claim 18, and therefore include all the limitations thereof, it is additionally respectfully submit that claims 19-35 are patentable over the prior art of record within the meaning of 35 U.S.C. § 103.



Having fully and completely responded to the Office Action, Applicants submit that all of the claims are now in condition for allowance, an indication of which is respectfully solicited.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicants' attorney at the telephone number shown below.

Respectfully submitted,

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